



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,806	12/11/2003	Enzo Leone	3687-63	5891
23117 7590 04/04/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER SOROUSH, LAYLA	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		04/04/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/732,806	Applicant(s) LEONE ET AL.	
	Examiner Layla Soroush	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1617

DETAILED ACTION

The Office Action is in response to the Preliminary Amendment filed December 3, 2003. Claims 1-13 are pending and are subject to the restriction requirements set forth herein.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a method of preparation of immunobiologically active drugs, classified in class 514, subclass 283.
- II. Claim 4, drawn to a method of homologous or eterologous transplantation of cellular culture of tissues comprising yohimbine, classified in class class 514, subclass 283.
- III. Claims 5-13, drawn to a method for stimulating the enhancement of immune response in a subject, classified in class class 514, subclass 283.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Group I is drawn to a method of preparation of immunobiologically active drugs while the invention of Group II is drawn to a method of homologous or eterologous transplantation of cellular culture of tissues comprising yohimbine. Preparations of immunobiologically active drugs such as yohimbine are different from

Art Unit: 1617

methods of homologous or heterologous transplantation of cellular culture of tissues comprising yohimbine.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. The searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. In searching Group I, Examiner will be focusing on the patentability of the preparation of immunobiologically active drugs, and not the method of homologous or heterologous transplantation of cellular culture of tissues comprising yohimbine of Group II. Conversely, in searching Group II, Examiner will be focusing on the patentability of the method of homologous or heterologous transplantation of cellular culture of tissues comprising yohimbine and not the preparation of immunobiologically active drugs. Thus, Groups I and II have been appropriately restricted on the basis of being independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Group I is drawn to a method of preparation of immunobiologically active drugs while the invention of Group III is drawn to a method for stimulating the enhancement of immune response in a subject. Preparations of immunobiologically

Art Unit: 1617

active drugs such as yohimbine are different from methods for stimulating the enhancement of immune response.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper. The searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. In searching Group I, Examiner will be focusing on the patentability of the preparation of immunobiologically active drugs, and not the method for stimulating the enhancement of immune response in a subject of Group III. Conversely, in searching Group III, Examiner will be focusing on the patentability of the method for stimulating the enhancement of immune response in a subject and not the preparation of immunobiologically active drugs. Thus, Groups I and III have been appropriately restricted on the basis of being independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of Group II is drawn to a method of homologous or eterologous transplantation of cellular culture of tissues comprising yohimbine while the invention of Group III is drawn to a method for stimulating the enhancement of immune response in a subject. A method of homologous or eterologous transplantation of cellular culture of

Art Unit: 1617

tissues comprising yohimbine is different from methods for stimulating the enhancement of immune response.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group III, restriction for examination purposes as indicated is proper. The searches in non-patent literature databases are extensive and do not overlap thus presenting a search burden to be searched together. In searching Group II, Examiner will be focusing on the patentability of the method of homologous or eterologous transplantation of cellular culture of tissues comprising yohimbine, and not the method for stimulating the enhancement of immune response in a subject of Group III. Conversely, in searching Group III, Examiner will be focusing on the patentability of the method for stimulating the enhancement of immune response in a subject and not the method of homologous or eterologous transplantation of cellular culture of tissues comprising yohimbine. Thus, Groups II and III have been appropriately restricted on the basis of being independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Election

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP 812.01). Since the restriction election is considered complex, a call to the attorney for a telephone election was not made.

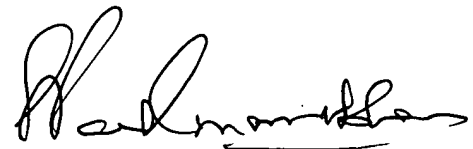
Art Unit: 1617

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER